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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,521	09/14/2004	Jean Berthier	258409US0X PCT	6722

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.  
1940 DUKE STREET  
ALEXANDRIA, VA 22314

EXAMINER
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WILDER, CYNTHIA B

ART UNIT	PAPER NUMBER
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1637

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/10/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/507,521

Applicant(s)

BERTHIER ET AL.

Examiner

Cynthia B. Wilder, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 11/2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicant's preliminary amendment filed on 9/14/2004 is acknowledged. Claims 1-18 have been amended. Claim 19 has been added. Claims 1-19 are pending.

#### ***Priority***

1. Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon an application filed in France on 03/25/2002. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the United States application was filed more than twelve months thereafter. Therefore, Applicant is afforded the instant filing 09/14/2004.***Specification***

2. The use of the trademark transfectam at page12 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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(a) Claims 1-14 and 19 are indefinite because the claim 1 does not recite a final process step which clearly relates back to the preamble such that it is clear that the goal of the preamble has been achieved and in what step. While minute details are not required in method claims, at least the basic steps must be recited in a positive, active fashion (see *ex parte Erlich*, 3 USPQ2d1011, p.1011 (Bd. Pat, Applicant. Int.1986). Clarification is required as to Applicant's intent.

(b) Claim 1 is indefinite at the recitation of "being capable of selectively fixing" because it cannot be determine if the limitation after "capable of" is a property of the interface layer or a separate entity. It is suggested amending the claim to recite more positive, active language by changing "capable of selectively fixing" to "which selectively fix" or some other language as supported by the specification.

(c) Claims 4 is indefinite at the recitation of "capable of selectively fixing" because it cannot be determine if the limitation after "capable of" is a property of the molecule or a separate entity. It is suggested amending the claim to recite more positive, active language by changing "capable of selectively fixing" to "which selectively fix" or some other language as supported by the specification.

(d) Claims 1 and 4 are vague and confusing at "selectively fixing" because the specification does not provide a limiting definition as to what is meant by "selectively fixing" and it cannot be determined Applicant's intent. Clarification is required.

(d) Claim 5 is indefinite at the recitation of "capable of fixing" because it cannot be determine if the limitation after "capable of" is a property of the molecule or groups or a separate entity. Additionally, the claims are confusing at "molecules comprising groups"

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because the specification does not provide a limiting definition of any "groups" and thus it cannot be determine what Applicant is making reference to. Clarification is required.

(e) Claim 10 lacks proper antecedent basis for "the hybridization" because none of the prior claims from which the claim 10 depends recite any steps of hybridization. It is suggested deleting "the" in front of "specific".

(f) Claim 14 is vague and confusing because it is unclear in the step 1 what "layer" applicant is making reference to. Additionally, the claim lacks a final process step which clearly relates back to the preamble. This it cannot be determined whether the goal of the preamble of "purifying a macromolecule or agglomerate" is achieved or not. While minute details are not required in method claims, at least the basic steps must be recited in a positive, active fashion (see *ex parte Erlich*, 3 USPQ2d1011, p.1011 (Bd. Pat. Applicant. Int.1986). It is suggested amending the claims such that Applicant's intent is clear.

(g) Claim 15 is vague and confusing because it is unclear in the step 1 what "layer" applicant is making reference. It is suggested amending the claim for clarity.

(h) Claims 16-18 are vague and confusing because the claims do not provide a clear nexus between the steps. First, it is unclear in the step 1 what layer Applicant is making reference to. Second, the final steps do not clearly identify what is actually being amplified. It is suggested amending the claims such that it is clear Applicant's intent.

#### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 4, 6, 9, 15 and 19 are rejected under 35 USC 102(b) as being anticipated by Unger (WO 01/64164 A2, September 2001). Regarding claim 1, Unger teaches a method comprising forming a stabilized dispersion of an emulsion type from a medium comprising said liquid sample and an interface layer, said interface layer capable of fixing macromolecules and reforming said interface layer by the resorption of the dispersion formed during said forming a stabilized dispersion (page 4, line 26 to page 5, line 22; page 13, line 25 to page 14, line 8 and page 34, line 23 to page 35, line 16).

Regarding claim 2, Unger teaches wherein said forming a stabilized dispersion is carried out by mechanical agitation of the medium comprising the liquid sample and said interface layer (page 34, line 23 to page 35, line 1, which teaches probe sonication).

Regarding claim 4, Unger teaches wherein the interface layer comprises at least one molecule capable of selectively fixing said macromolecules (page 34, line 23 to page 35, line 16).

Regarding claim 6, Unger teaches wherein the macromolecules is selected from the group consisting of nucleic acids, proteins and antigens (page 12, lines 1-4 and page 13, lines 11-17).

Regarding claim 9, Unger teaches wherein the macromolecule is DNA (page 13, line 15).

Regarding claim 15, Unger teaches a method for the detection of a macromolecule comprising concentrating within a layer, said macromolecule according to claim 1 and detecting said macromolecule (see examples).

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Regarding claim 19, Unger teaches wherein said molecule is a surfactant molecule (page 15, lines 4-28). Therefore, Unger meets the limitations of the claims noted above.

7. Claims 1-2, 4-6, 9, 10, 14, 15 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Jaschke et al {Jaschke, herein} (Nucleic acids research, vol. 22, No. 10, pages 1880-1884).

Regarding claim 1, Jaschke teaches a method comprising forming a stabilized dispersion of an emulsion type from a medium comprising said liquid sample and an interface layer, said interface layer capable of fixing macromolecules and reforming said interface layer by the resorption of the dispersion formed during said forming a stabilized dispersion (page 1880-1881, section entitled "MATERIALS AND METHODS"; and figure 1).

Regarding claim 2, Jaschke teaches wherein said forming a stabilized dispersion is carried out by mechanical agitation of the medium comprising the liquid sample and said interface layer (page 1881, col. 1, line 1).

Regarding claim 4, Jaschke teaches wherein the interface layer comprises at least one molecule capable of selectively fixing said macromolecules (page 1880-1881, section entitled "MATERIALS AND METHODS"; and figure 1).

Regarding claim 5, Jaschke teaches wherein the fixing of the macromolecule is by chemical affinity (pages 180-1881, section entitled "MATERIALS AND METHODS").

Regarding claim 6, Jaschke teaches wherein the macromolecules is nucleic acids (page 1880-1881, section entitled "MATERIALS AND METHODS").

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Regarding claim 9, Jaschke teaches wherein the macromolecule is DNA (page 1880-1881, section entitled "MATERIALS AND METHODS").

Regarding claim 10, Jaschke teaches wherein the macromolecule is DNA and the molecule capable of fixing the DNA is functionalized with a probe to allow specific hybridization of the DNA (page 1880-1881, section entitled "MATERIALS AND METHODS").

Regarding claim 14, Jaschke teaches a method for the purification of a macromolecule, the method comprising concentrating said macromolecules within a layer using the method according to claim 1 and then eliminating the liquid sample depleted of said macromolecule (page 1880-1881, section entitled "MATERIALS AND METHODS"; note\* the reference teaches wherein the layers are centrifuge and separated into separate tubes).

Regarding claim 15, Jaschke teaches a method for the detection of a macromolecule comprising concentrating within a layer, said macromolecule according to claim 1 and detecting said macromolecule (page 1880-1881, section entitled "MATERIALS AND METHODS").

Regarding claim 19, Jaschke teaches wherein said molecule is a surfactant molecule (page 1880-1881, section entitled "MATERIALS AND METHODS"; and figure 2). Therefore, meets the limitations of the claims noted above. Therefore, Jaschke meets the limitations of the claims noted above.

8. Claims 1, 4-6, 9-10 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Ijiro et al (cited on IDS). Regarding claim 1, Ijiro et al. teach a method comprising forming a stabilized dispersion of an emulsion type from a medium comprising said liquid sample and an interface layer, said interface layer capable of fixing macromolecules and reforming said



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interface layer by the resorption of the dispersion formed during said forming a stabilized dispersion (col. 2, lines 46-60; col. 3, line 35 to col. 4, line 61).

Regarding claim 4, Ijiro et al teach wherein the interface layer comprises at least one molecule capable of selectively fixing said macromolecules (col. 2, lines 46-60; col. 3, line 35 to col. 4, line 61).

Regarding claim 5, Ijiro teaches wherein the fixing of the macromolecule is by chemical affinity ((col. 2, lines 46-60; col. 3, line 35 to col. 4, line 61).

Regarding claim 6, Ijiro et al teaches wherein the macromolecules are nucleic acids (col. 3, lines 55-56).

Regarding claim 9, Ijiro et al teaches wherein the macromolecule is DNA (col. 3, lines 55-56).

Regarding claim 10, Ijiro et al teaches wherein the macromolecule is DNA and the molecule capable of fixing the DNA is functionalized with a probe to allow specific hybridization of the DNA (col. 3, line 54 to col. 4, line 13).

Regarding claim 15, Ijiro et al teaches a method for the detection of a macromolecule comprising concentrating within a layer, said macromolecule according to claim 1 and detecting said macromolecule (col. 4, lines 14-37). Therefore, Ijiro et al meet the limitation of the claims recited above.

### ***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claim 1-2, 6, 8, 9, 16 and 17 are rejected under 35 U.S.C. 102(a) and 35 U.S.C. 102(e) as being anticipated by Clear et al. (US 6,750,261 June 15, 2004). Regarding claims 1, 2, 8 and 9, Clear et al teach a method comprising forming a stabilized dispersion of foam from a medium comprising a liquid sample and interface layers and reforming said interface layer by the resorption of the dispersion formed during said forming a stabilized dispersion, wherein said dispersion is due to agitation and wherein said macromolecule is DNA or colloidal particle (col. 5, line 22 to col. 9, lines 42-46 and col. 16, lines 2-7 and 57-68).

Regarding claims 16 and 17 teach a method of using high internal phase emulsion foams for removing macromolecules in a layer and using said macromolecules (DNA) in amplification reactions (col. 9, line 42-46; col. 12, lines 37-45; and col. 17, lines 28-58). Therefore, Clear et al meet the limitation of the claims recited above.

### ***Conclusion***

11. No claims are allowed. However, some of the claims were not rejected under prior art. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner can normally be reached on a flexible schedule.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Cynthia B. Wilder, Ph.D.

Patent Examiner

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1/8/07